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510(k) Summary of Safety and Effectiveness
VariAx™ Distal Fibula Plate

JUL 18 2008

Proprietary Name:	VariAx™ Distal Fibula Plate
Common Name:	Bone plates and screws
Classification Name/Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 KTT
Proposed Regulatory Class:	Class II
For Information contact:	Andrea Dwyer, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6250 Fax: (201) 831-6038
Date Summary Prepared:	May 5, 2008

Description:

This submission is a line extension to the Stryker® Plating System. The components of the VariAx™ Distal Fibula Plate are intended to add a different type of plate to the Stryker® Plating System portfolio.

Indications:
The VariAx™ Distal Lateral Fibula Plate is intended for use in internal fixation of the distal fibula.

Substantial Equivalence:

The VariAx™ Distal Fibula Plate is substantially equivalent to the Stryker® Foot, Profyle®, Universal Distal Radius System, and the Synthes® Small Fragment Locking Compression Plate (LCP) System in regards to intended use, design, materials, and operational principles as a fracture plating system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Ms. Andrea Dwyer
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, NJ 07430

JUL 18 2008

Re: K081284
Trade/Device Name: VariAx™ Distal Fibula Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation ~~Appliances and accessories~~
Regulatory Class: Class II
Product Code: KTT
Dated: May 5, 2008
Received: May 6, 2008

Dear Ms. Dwyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081284

Device Name: VariAx™ Distal Fibula Plate

Indications for Use:

The VariAx™ Distal Lateral Fibula Plate is intended for use in internal fixation of the distal fibula.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

~~Concurrence of CDRH, Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081284